

### **REMARKS**

Claims 39-43, 70 and 80 - 86 are in the case. Original claims 36-38 were canceled by amendment in favor of new claims 81-86.

No new matter has been added.

Applicants gratefully acknowledge removal of the objection to claim 39 and the rejections of claims 42 and 43 under 35 USC § 112, 2<sup>nd</sup> paragraph as well as the entry of the amendment to page 1 of the specification correcting the claim to priority. Applicants also acknowledge that, other than these stated amendments, no other amendments to the claims or specification have been entered.

All claims stand rejected variously under 35 USC § 112 and 103.

A Notice of Appeal was filed on October 9, 2003. This amendment accompanies a Request for Continuing prosecution including the requisite fee and therefore withdraws the Notice of Appeal.

#### ***Claim Rejections – 35 USC § 112***

Claims 82, 84 and 86 are rejected under 35 USC § 112, first paragraph for lack of enablement. In the action mailed 4/9/03, the Examiner argues that while the specification is enabling for a method for conditionally activating a transgene in a second generation plant when the promoter of the third recombinase element is not active in the common germline (using combinations of two site-directed recombination systems to cause developmentally staggered site-specific recombinations to control transgene expression), the specification is not enabling when the third recombinase promoter is active in the germline. Applicants traverse. In the Advisory action mailed 10/20/03 the examiner notes that there is lack of clarity with respect to what is meant by “floral germline promoters” as the term is not specifically defined.

Claims 82, 84 and 86 are now amended to include the limitation that; P1 = a germline promoter; P2 = a floral specific germline promoter and P3 = a promoter that is not expressed in floral tissue, i.e., a non-floral promoter. Examples of germline promoters include 35S (non-floral) and AP3 (floral specific).

The characteristics of P2 are that it is expressed in floral tissue and in the germline. The claim has been amended to include floral common germline, floral male germline and floral female germline promoters as defined on page 17, line 29 and page 18, line 1.

Examples of a non-floral tissue promoter includes for example the senescence-specific promoter (SAG) or the seed storage protein promoters such as promoters for napin, cruciferin, beta-conglycinin, and phaseolin. Under these conditions, i.e., when the expression specificities of P2 and P3 promoters do not overlap, applicants submit that the activation of P3: TG will only occur in the second generation plant and not in the first generation germline cells.

***Claim Rejections – 35 USC § 103***

9. Claims 39-41, 70 and 80 remain rejected under 35 U.S.C. §103(a) as being unpatentable over Odell et al. “A” (*Mol. Gen. Genet.* 223: 369-378 (1990)), in combination with Lloyd et al. (*Mol. Gen. Genet.* 242: 653-657 (1994)), the present state of the art, and Odell et al. “B” (Use of Site-Specific Recombination Systems in Plants, in Homologous Recombination and Gene Silencing in Plants; Paszkowski, J., Ed.; Kluwer: Dordrecht, Germany, 1994; pp 219-270).

The rejection of the claims under 35 U.S.C. §103(a) is maintained for reasons of record. Specifically the Examiner argues that it would have been obvious to one skilled in the art to combine the teachings concerning single site-specific recombination systems (Odell et al. A and Lloyd et al.) with the teachings of specific promoters and transgenes (Applicant’s admitted state of the prior art), and further combine these teachings with the teachings of the wide range of applications of single site-specific recombination systems (Odell et al. B) to derive the present invention. Applicants traverse.

Applicants previous arguments relating to this rejection have been considered but are not found persuasive. Specifically applicants have argued that the art only teach instances of the single site specific recombination as opposed to the multiple use of site specific recombination of the invention. The examiner suggests that the specificity of the SSR’s taught in the art (Odell et al B) suggest that more than one SSR could be active and useful in a plant.

Applicants again submit that the level of predictability for the function of several independent SSR systems in one or more plants is low and one of skill in the art could not a priori predict with any reasonable certainty that combinations of these systems would indeed work. The expression of multiple SSR systems in multiple tissue types has not been demonstrated prior to applicants invention and one of skill in the art would not have had a reasonable expectation of success given the state of the art.

In regard to the references cited by Applicants in support of the assertion that expression of recombinases may be toxic; Applicants recognize that the expression systems addressed in these references are in *Drosophilla* and Mammalian tissue, however are relevant here to support the notion of unpredictability in eukaryotic plant cells.

Applicants again submit, with respect to the specific embodiment of the invention (claims 81-86) providing for the expression of a P3 driven transgene expressed only in a second generation plant, the art is silent as to how this selective expression could be achieved. For selective transgene expression in second generation plants to occur not only must the inherent unpredictability of recombinase expression be overcome but the combination of promoters with requisite spatial and temporal expression specificities must be identified so as to produce the desired effect. This combination of promoters is clearly not suggested or anticipated in the art, but has been elucidated in Applicant’s invention.

Should there be any fee due in connection with the filing of this Response and Amendment please charge such fee to Deposit Account No. 04-1928 (E. I. du Pont de Nemours and Company).

In view of the foregoing, allowance of the above-referenced application is respectfully requested.

Respectfully submitted,



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